Guidance for Compliance with 45 CFR 46 in Classifying Public Health Activities as Research and to Protect Human Subjects

	Research	Practice (nonresearch)
Definition	"...systematic investigation, including research development, testing, and evaluation, **designed** to develop or contribute to generalizable knowledge." (ref. 45 CFR 46)	May use scientific methods to identify and control a health problem with benefits for the study participants or their communities.
Primary Intent	To generate new or generalizable knowledge (information that can be applied in other settings)	To benefit study participants or the communities from which they come
Methodology	Scientific principles and methods used. Hypothesis testing/generating Knowledge is generalizable	Scientific principles and methods may be used. Hypothesis testing/generating Knowledge may be generalizable
Examples		
Surveillance Projects	 Scope of data is broad Analytic analyses Hypothesis testing Subsequent studies using cases	Regular, ongoing collection and analyses to measure occurrence of health problem (disease registry) Scope of data is health condition or disease, demographics, and known risk factors Invokes public health mechanisms to prevent or control disease or injury
Emergency Response	Samples stored for future use Additional analyses performed beyond immediate problem Investigational drugs tested	Solves an immediate health problem No testing of methods or interventions
Program Evaluation	Test an intervention Systematic comparison of standard and nonstandard interventions	Assess success of established intervention Evaluation information used for feedback into program (management)

Source: Guidelines for Defining Public Health Research and Public Health Non-Research, revised June, 1999
Applies to research conducted by CDC staff whether funded by CDC or another entity and to research funded by CDC to other entities. Activities classified as research require IRB review if the (1) involve human subjects and (2) do not meet the criteria for exemption for IRB approval.